

SPACER FOR SLING DELIVERY SYSTEM

Related Applications

This application claims the benefit of and priority to provisional patent application serial No. 60/434,167, filed December 17, 2002, and provisional patent application serial No. 60/449,465, 5 filed February 24, 2003, the entirety of which is incorporated herein by reference.

Technical Field

[0001] The invention relates generally to systems, and related methods and devices, for delivering an implant, such as a surgical sling, to an anatomical site in the body of a patient.

Background of the Invention

10 **[0002]** Stress urinary incontinence (SUI) affects primarily women and is generally caused by two conditions, intrinsic sphincter deficiency (ISD) and hypermobility. These conditions may occur independently or in combination. In ISD, the urinary sphincter valve, located within the urethra, fails to close properly (coapt), causing urine to leak out of the urethra during stressful activity. Hypermobility is a condition in which the pelvic floor is distended, weakened, or 15 damaged, causing the bladder neck and proximal urethra to rotate and descend in response to increases in intra-abdominal pressure (e.g., due to sneezing, coughing, straining, etc.). The result is that there is an insufficient response time to promote urethral closure and, consequently, urine leakage and/or flow results.

15 **[0003]** Improved systems and methods for treating SUI are needed.

20 Summary of the Invention

[0004] The invention addresses deficiencies of the prior art by providing devices and methods for facilitating spacing away from a sling a sleeve, which at least partially encloses the sling. Such sling/sleeve configurations may be implanted into a patient's body, for example, for the treatment of urinary incontinence. According to a particular embodiment, the sling/sleeve 25 combination is delivered to a mid-urethral location of a patient. The methods and systems of the invention simplify cutting the sleeve at an intermediate location by a medical operator, while also reducing the likelihood of the medical operator inadvertently cutting the sling. Once the sleeve is cut at an intermediate location, preferably via the vagina, the sleeve may be removed

from the patient, for example, by pulling on sleeve ends. According to another advantage, the systems and methods of the invention space a intermediately located portion of the sling away from patient tissue, such as periurethral tissue, to make it easier for a medical operator to position the sling/sleeve combination without traumatizing the periurethral tissue.

5 [0005] The invention, which may be employed with any suitable sleeve/sling combination, in various aspects, features a spacer for positioning away from a portion of a sling a portion of a sleeve that at least partially encloses the sling; methods of making such a spacer; medical kits including such a spacer; and methods of treating a damaged, weakened, sagging, herniated, or prolapsed portion of a patient's body using such a spacer.

10 [0006] According to one embodiment of the invention, the spacer includes a tube having first and second ends and a lumen extending between the first and second ends. Preferably, the tube is formed into a V-shape, for example, by bending the tube at its midpoint such that the tube has first and second tube portions. When employed, the sleeve traverses through the lumen of the first and second tube portions and forms a sleeve bridge between the first and second tube ends

15 across the open end of the V-shape. The tube can also include an aperture at the vertex of the first and second tube portions. The sleeve can pass, for example, into the lumen in the first tube section via the aperture, out the first tub end, into the second tube end, through the second tube section and out the aperture, thus forming the sleeve bridge between the first and second tube ends. The spacer can also include an anchoring mechanism for anchoring the sling in the tube.

20 In some configurations, the anchoring mechanism includes a suture that passes through the lumen to form a suture bridge across the first and second tube ends. According to one feature, the spacer includes a truss extending between the first and second tube portions.

[0007] In another embodiment, the spacer can include a sling engaging member. The sling engaging member facilitates the positioning of a portion of a sling away from a portion of a sleeve. In one embodiment, the sling engaging member includes a slot for traversal by the sling. The sling slot can include an anchoring mechanism for holding the sling such that the sling does not move during placement of the sling at a site in the body. The anchoring mechanism can be, for example, teeth such as tapered teeth or a cantilever beam such as a beam having an inverted T-shape.

25 [0008] The spacer may also include a sleeve engaging member. The sleeve engaging member facilitates the positioning of a portion of a sleeve away from a portion of a sling. In one

embodiment, the sleeve engaging member includes a slot for traversal by the sleeve. The sleeve engaging member serves to hold the sleeve in a position away from the sling so that the medical operator can cut the sleeve without inadvertently also cutting the sling.

[0009] In some configurations, the spacer also includes a tissue spacing member for spacing the sling away from a patient's tissue. As mentioned above, such spacing makes it easier for a medical operator to position the sling during delivery. Preferably the tissue spacing member has a concave surface for supporting tissue, such as periurethral tissue at a mid-urethral location in a patient's body.

[0010] The spacer of the invention may include an indicator for indicating to the medical operator a direction in which the spacer is to be removed. The indicator can also include a handle for facilitating spacer removal. In one configuration, the indicator is shaped like an arrowhead, with the tip of the arrowhead indicating the direction of removable. In other configurations, the arrowhead is large enough to form a handle to facilitate spacer removal.

[0011] According to a further embodiment, the spacer of the invention includes a receptacle for traversal by a portion of the sleeve. The spacer may also include an insert for mating within the receptacle and holding the portion of the sleeve in place within the receptacle. The receptacle may be of any suitable shape. Preferably, it is substantially U-shaped and the insert is appropriately shaped for mating engagement with the receptacle.

[0012] In some embodiments, the spacer includes an elongated shaft extending between the sleeve engaging member and the sling engaging member. The presence of an elongated shaft in the spacer is advantageous as it facilitates spacing of the sleeve away from the sling and has the added feature of making it easier for a medical operator to remove the spacer from the patient's body following sling placement. In one embodiment, the elongated shaft includes a proximal end and a distal end and a channel extending between the proximal end and the distal end. The sling is positioned at the distal end of the elongated shaft and the sleeve is passed through the channel to the proximal end where a sleeve engaging member holds the sleeve in place, and/or forms a sleeve bridge to facilitate cutting of the sleeve by a medical operator.

[0013] In an alternative configuration the sling engaging member includes a pin extending from the spacer. In one such configuration, the spacer includes a first elongated shaft extending between the pin and the sleeve engaging member and a second elongated shaft extending between the pin and the sleeve engaging member, and the first and second elongated members

each include a channel for passage of the sleeve. The distal ends of the elongated shafts further include a sleeve engaging member, for example, for holding the sleeve in place and/or for forming a sleeve bridge for facilitating cutting of the sleeve by a medical operator.

[0014] In another aspect, the invention provides a sling delivery system including a sling

5 assembly and a spacer, as described above. The sling assembly includes an elongated sling (i.e., a mesh sling) and a sleeve enclosing at least a portion of the sling. For example, a sling system can include a sling, a sleeve covering at least a portion of the sling, and a spacer, wherein the sleeve comprises first and second sides, the first side having first and second slit-shaped apertures intermediately located between first and second ends of the sleeve, the sling threads out 10 of the sleeve through the first slit-shaped aperture and back into the sleeve through the second slit-shaped aperture creating a mid-length sleeve loop, and the spacer is positioned to space the sling away from the mid-length sleeve loop. In this embodiment, the spacer can be a tube, such as a substantially flat tube which includes an aperture for sighting a cutting line through the spacer and sleeve loop to separate the sleeve into portions that may be removed from about the 15 sling, and wherein the sleeve loop is partially secured within the interior of the tube.

[0015] In one embodiment of this aspect of the invention, the sleeve includes first and second ends and the spacer is positioned intermediate to the first and second ends. In another embodiment, the sling includes first and second sides, the sleeve includes first and second sides, and the spacer is disposed between the second side of the sling and the second side of the sleeve.

20 According to various configurations, the sling/sleeve combination may terminate in any suitable fashion.

[0016] The foregoing and other objects, aspects, features, and advantages of the invention will become more apparent from the following description.

Brief Description of the Drawings

25 [0017] In the drawings, like reference characters generally refer to the same parts throughout the different views. Also, the drawings are not necessarily to scale, emphasis instead generally being placed upon illustrating the principles of the invention.

[0018] FIG. 1 depicts a perspective side view of a spacer according to an illustrative embodiment of the invention employed with an exemplary sling assembly section.

30 [0019] FIG. 2 depicts a perspective side view of a spacer according to another illustrative embodiment of the invention employed with an exemplary sling assembly section.

[0020] FIG. 3A depicts a perspective side view of a spacer according to another illustrative embodiment of the invention employed with an exemplary sling assembly section.

[0021] FIG. 3B depicts a perspective front view of the spacer and sling assembly section of FIG. 3A.

5 [0022] FIG. 4A depicts a perspective top view of a spacer according to another illustrative embodiment of the invention.

[0023] FIG. 4B depicts a perspective bottom view of the spacer of FIG. 4A.

[0024] FIG. 4C depicts a perspective top view of the spacer of FIG. 4A employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

10 [0025] FIG. 4D depicts a perspective bottom view of the illustrative spacer and sling assembly section of FIG. 4C.

[0026] FIG. 4E depicts a perspective side view of the illustrative spacer and sling assembly section of FIG. 4C.

[0027] FIG. 5 depicts a perspective side view of the spacer and sling assembly section of FIGS. 15 4C-4E employing according to another illustrative embodiment of the invention.

[0028] FIG. 6A depicts a perspective side view of the spacer and sling assembly section of FIG. 4C, positioned adjacent the urethra of a patient.

[0029] FIG. 6B depicts a perspective side view of the illustrative spacer and sling assembly section of FIG. 6A after the sleeve bridge is cut.

20 [0030] FIG. 7A depicts a perspective top view of a spacer according to another illustrative embodiment of the invention.

[0031] FIG. 7B depicts a perspective top view of the illustrative spacer of FIG. 7A employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

25 [0032] FIG. 8A depicts a perspective front view of a spacer according to another illustrative embodiment of the invention.

[0033] FIG. 8B depicts a perspective side view of the illustrative spacer of FIG. 8A employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

30 [0034] FIG. 9 depicts a perspective side view of a spacer according to another illustrative embodiment of the invention.

[0035] FIG. 10A depicts a perspective side view of a spacer according to another illustrative embodiment of the invention.

[0036] FIG. 10B depicts a plan view of the illustrative spacer of FIG. 10A employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

5 [0037] FIG. 11A depicts a perspective top view of a spacer according to another illustrative embodiment of the invention.

[0038] FIG. 11B depicts a perspective side view of the illustrative spacer of FIG. 11A, bent at its mid-point according to illustrative embodiment of the invention.

10 [0039] FIG. 11C depicts a perspective side view of the illustrative spacer of FIG. 10B employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

[0040] FIG. 11D depicts a perspective side view of an anchoring mechanism according to an illustrative embodiment of the invention employed with the illustrative spacer and sling assembly of FIG. 11C.

15 [0041] FIG. 11E depicts a bottom view of the spacer of FIG. 11A further formed to include a truss according to an illustrative embodiment of the invention.

[0042] FIG. 11F depicts a perspective top view of the illustrative spacer of FIG. 10E.

[0043] FIG. 11G depicts a perspective side view of the illustrative spacer of FIG. 10F, bent at its mid-point according to another illustrative embodiment of the invention.

20 [0044] FIG. 11H depicts a perspective side view of the illustrative spacer of FIG. 10G employed with an exemplary sling assembly section according to an illustrative embodiment of the invention.

[0045] FIG. 12 depicts a perspective side view of a spacer and a sling assembly according to an illustrative embodiment of the invention.

25 [0046] FIG. 13 depicts a perspective side view of the spacer and sling assembly of FIG. 12 where the sling ends are held in the spacer.

[0047] FIG. 14 depicts a perspective side view of the spacer and sling assembly of FIG. 12 according to a further illustrative embodiment of the invention.

30 [0048] FIG. 15 depicts an approach to removing the spacer of FIG. 12 according to an illustrative embodiment of the invention.

Illustrative Description of the Invention

[0049] In general, the invention pertains to systems, methods, and devices relating to delivering a sling to an anatomical site in the body of a patient, for example, the periurethral tissues of the patient in the treatment of female urinary incontinence. More particularly, the invention is

5 directed to various configurations of spacers for spacing away from the sling at least a portion of a sleeve that at least partially encloses the sling. By spacing a portion of the sleeve away from the sling, the spacers of the invention enable a medical operator to more easily cut the sleeve, without damaging the sling, so that the sleeve may be removed from a patient's body, while leaving the sling in place. Another feature of some spacer configurations of the invention is that

10 the spacer acts to space a portion of the sling away from patient tissue, for example, periurethral tissue. By spacing a portion of the sling away from the patient tissue, the spacer of the invention makes it easier for the medical operator to position the sling without traumatizing patient tissue that would otherwise rub against the sling during positioning. As a preliminary matter it should be noted that the various illustrative spacer configurations discussed in further detail below may

15 be employed with any suitable sling/sleeve configuration. By way of example, the spacers of the invention may be employed with sleeves having one or more apertures. They may also be employed with sleeves having a generally unitary construction or alternatively, with sleeves formed from multiple discrete sections. Without limitation, exemplary sling/sleeve configurations that may be operable with illustrative embodiments of the invention may be found

20 in U.S. patent application entitled Medical Slings, to Rao et al, Attorney Document No.: BSC-265, filed on even day herewith; U.S. patent application entitled Medical Slings, to Chu, Attorney Document No.: BSC-276, filed on even day herewith; U.S. provisional patent application entitled Surgical Slings, to Li et al, Attorney Document No.: BSC-279PR, filed on even day herewith, U.S. patent application entitled Systems, Methods and Devices relating to

25 Delivery of Medical Implants, to Chu et al., Attorney Document No.: BSC-267-1; BSC-267-2; BSC-267-3; and BSC-267-4, filed on even day herewith, U.S. patent application entitled Medical Implant, to Chu et al., Attorney Document No.: BSC-255, filed on even day herewith, U.S. provisional patent application serial No. 60/403,555; U.S. provisional patent application serial No. 60/465,722; U.S. patent application serial No. 10/460,112; and U.S. patent application serial

30 No. 09/096,983, the entire contents of which are incorporated herein by reference.

[0050] As another preliminary matter, the ends of the slings or sleeves employed may terminate in any suitable configurations or structures such as loops, for example, apertures, male and female connectors, guide tubes and the like. Some exemplary sling/sleeve termination configurations and structures are disclosed in U.S. patent application serial No. 10/325,125; U.S. 5 provisional patent application serial No. 60/418,827; U.S. provisional patent application serial No. 60/418,642; U.S. provisional patent application serial No. 60/434,167; and U.S. provisional patent application serial No. 60/403,555; the disclosures of which are incorporated herein by reference.

[0051] As a further preliminary matter, it should be noted that the various illustrative spacer 10 configurations may be employed with any suitable sling delivery system. By way of example, the spacers of the invention may be employed with any sling/sleeve configurations and delivery systems appropriate for treating urinary incontinence. Such delivery systems include, for example, those delivery systems configured for supra-pubic, pre-pubic, transvaginal or transobturator approaches. Without limitation, exemplary delivery systems, slings, sling 15 attachments and methodologies that may be employed in combination with the spacers of the invention can be found in U.S. patent application serial No. 10/093,498; U.S. patent application serial No. 10/093,398; U.S. patent application serial No. 10/093,450; U.S. patent application serial No. 10/094,371; U.S. patent application serial No. 10/094,352; U.S. patent application serial No. 10/093,424; U.S. provisional patent application serial No. 60/403,555; U.S. patent application serial No. 09/916,983; U.S. provisional patent application serial No. 60/465,722; U.S. provisional patent application serial No. 60/418,827; U.S. provisional patent application serial No. 60/418,642; U.S. provisional patent application serial No. 60/274,843; U.S. 20 provisional patent application serial No. 60/286,863; and U.S. provisional patent application serial No. 60/434,167, the disclosures of which are incorporated herein by reference.

[0052] Turning now to illustrative embodiments of the invention, FIG. 1 depicts a perspective 25 side view of a spacer 102 according to an illustrative embodiment of the invention employed with an exemplary sling assembly section 100. As depicted, the sling assembly 100 includes a mesh sling 104 partially enclosed by a sleeve 106. Although, the sleeve 106 may be any suitable sleeve, illustratively it is shown as having a first sleeve wall 108 and a second sleeve wall 110, 30 with the mesh sling 104 located between the first 108 and second 110 sleeve walls. The first sleeve wall 108 includes a discontinuity forming a gap 112 exposing an intermediate portion 114

of the mesh sling 104. The particular spacer 102 in this embodiment is generally rectangular in shape and spaces an intermediately located portion 116 of the sleeve wall 110 away from the intermediate sling portion 114. The spacer 102 is positioned to create a loop 118 in the intermediate portion 116 of the sleeve wall 110. As described below in further detail with regard

5 to FIGS. 4-11, the spacer 102 can be operatively engaged with the intermediate portion 116 of the sleeve wall 110 in a variety of ways. By way of example, the spacer 102 may include any number of slots, channels or protuberances to engage the sleeve wall 110. Alternatively, the spacer 102 can be bonded to or interconnected via suture with the sleeve wall 110.

10 [0053] In operation, once the sling assembly 100 is positioned within the body of a patient, for example under a patient's mid-urethra, a medical operator can insert a pair of scissors into the loop 118 to cut the sleeve 106, without risking accidentally cutting the sling 104. With the sleeve 106 so cut, the sleeve ends 120 and 122 may be pulled to remove the sleeve 106 from the patient's body, while leaving the sling 104 in place. The spacer 102 may be removed, for example, via the patient's vagina.

15 [0054] FIG. 2 depicts a perspective side view of a spacer 202 according to another illustrative embodiment of the invention employed with an exemplary sling assembly section 200. The illustrative spacer 202 of FIG. 2 is substantially cylindrical in shape. In a similar fashion to FIG. 1, the sling assembly 200 includes a mesh sling 204 partially enclosed by a sleeve 206. As in the case of the sleeve 106, the sleeve 206 may be any suitable sleeve. Illustratively, it is shown as
20 having a first sleeve wall 208 and a second sleeve wall 210, with the mesh sling 204 located between the first 208 and second 210 sleeve walls. The first sleeve wall 208 includes a discontinuity forming a gap 212 exposing an intermediate portion 214 of the mesh sling 204. The particular spacer 202 is generally cylindrical in shape and spaces an intermediately located portion 216 of the sleeve wall 210 away from the intermediate sling portion 214. The spacer 202 is positioned to create a loop 218 in the intermediate portion 216 of the sleeve wall 210. As in the case of the embodiment of FIG. 1, and as described below in further detail with regard to FIGS. 25 4-11, the spacer 202 can be operatively engaged with the intermediate portion 216 of the sleeve wall 210 in a variety of ways. By way of example, the spacer 202 may include any number of slots, channels or protuberances to engage the sleeve wall 210. Alternatively, the spacer 202 can
30 be bonded to or interconnected via suture with the sleeve wall 210. In some illustrative

configurations, the spacer 202 is flattened to form a friction based attachment to a portion of the intermediate portion 216 of the sleeve wall 210.

[0055] Once the sling assembly 200 is positioned within the body of a patient, for example under a patient's mid-urethra, a medical operator can cut through the spacer 202 and thus, cut through 5 the intermediate portion 216 of the sleeve wall 210, without risking accidentally cutting the sling 204. As in the case of the embodiment of FIG. 1, with the sleeve 206 so cut, the sleeve ends 220 and 222 may be pulled to remove the sleeve 206 from the patient's body, while leaving the sling 204 in place. The spacer 202 may be removed, for example, via the patient's vagina.

[0056] FIG. 3A depicts a perspective side view of a spacer 302 according to another illustrative 10 embodiment of the invention employed with an exemplary sling assembly section 300, and FIG. 3B depicts a perspective front view of the spacer 302 and sling assembly section 300 of FIG. 3A. Referring to FIGS. 3A and 3B, in a similar fashion to the embodiments of FIGS. 1 and 2, the sling assembly 300 includes a mesh sling 304 partially enclosed by a sleeve 306. As in the case of the sleeve 206, the sleeve 306 may be any suitable sleeve. Illustratively, it is shown as having 15 a first sleeve wall 308 and a second sleeve wall 310, with the mesh sling 304 located between the first 308 and second 310 sleeve walls. The first sleeve wall 308 includes a discontinuity forming a gap 312 exposing an intermediate portion 314 of the mesh sling 304.

[0057] The particular spacer 302 is generally flat in shape and includes first 303 and second 305 sides between which an intermediately located portion 316 (not visible) of the sleeve wall 310 is 20 sandwiched and spaced away from the intermediate sling portion 314. According to the illustrative embodiment, the tab spacer 302 is closed along its top edges 307 and 309 and open along its intermediate edges 311 and 313. The bottom edge 315 is left open until after the intermediately located portion 316 of the sleeve wall 310 is inserted in between the first 303 and second 305 sides of the spacer 302. Subsequent to insertion of the intermediate portion 316, the 25 bottom edge 315 of the spacer 302 is bonded, for example, using heat or glue, together and to that portion of the intermediate portion 316 of the sleeve wall 310 located near the bottom edge 315 of the spacer 302. With the bottom edge 315 so bonded, the spacer 302 may be removed by cutting from one intermediate edge 311 to the other intermediate edge 313, and then sliding the remaining portion of the spacer 302 off the intermediate portion 316 of the sleeve wall 310. The 30 illustrative spacer 302 also includes an aperture 317, which indicates a location for making the cut between the intermediate edges 311 and 313. The aperture 317 also enables a person to view

the intermediate portion 316 of the sleeve wall 310 to verify proper installation into the spacer 102.

[0058] Once the sling assembly 300 is positioned within the body of a patient, for example under a patient's mid-urethra, a medical operator can cut through the spacer 302 as described above 5 and thus, cut through the intermediate portion 316 of the sleeve wall 310, without risking accidentally cutting the sling 304. As in the case of the embodiment of FIGS. 1 and 2, with the sleeve 306 so cut, the sleeve ends 320 and 322 may be pulled to remove the sleeve 306 from the patient's body, while leaving the sling 304 in place. The spacer 302 may be removed, for example, via the patient's vagina.

[0059] FIG. 4A depicts a perspective top view of a spacer 400 according to another illustrative embodiment of the invention, and FIG. 4B depicts a perspective bottom view of the spacer 400 of FIG. 4A. FIGS. 4C-4E depict various views of the spacer 400 employed with an exemplary sling assembly 402. Referring to FIGS. 4A-4D, the spacer 400 includes a first side 404; a second side 408; a top side 410; a bottom side 412; a front side 414; and a back side 416 (*i.e.*, a side that is closest to an operator of a delivery system). The spacer 400 also includes a sling engaging member, 418, formed as a sling slot positioned underneath the top side 410, and a sleeve engaging member 420, formed as two sleeve slots 420A and 420B positioned on the first side 404 of the spacer 400, and two sleeve slots 420C and 420D positioned on the second side 408 of the spacer 400. Alternatively, the spacer 400 may include any number of sides with any number 15 of sling engaging members 418 or sleeve engaging members 420 positioned on any side.

[0060] The illustrative spacer 400 is constructed of a rigid medical grade plastic material or, alternatively, of other suitable rigid materials. However, in alternative embodiments, the spacer 400 may be formed from more flexible suitable materials. The top side 410 of the spacer 400 can serve as a tissue spacing member 422 for spacing the sling 403 of the sling assembly 402 20 away from the patient's tissue.

[0061] The illustrative spacer 400 also includes an indicator 424, which indicates the direction in which the spacer 400 should be removed following implantation of the mesh sling 403 at an anatomical site in the patient's body. The indicator 424, optionally, includes or is sized big enough to be used as a handle. Such a handle may be located on any of the sides of the spacer 30 400.

[0062] Referring particularly to FIGS. 4C-4E, the spacer 400 is depicted in various views employed with the sling assembly section 402. As in the case of previously described embodiments, the sling assembly 402 includes a mesh sling 403 partially enclosed by a sleeve 405. As in the case of the sleeves 106, 206 and 306, the sleeve 405 may be any suitable sleeve.

5 Illustratively, it is shown as having a first sleeve wall 407 and a second sleeve wall 409, with the mesh sling 403 located between the first 407 and second 409 sleeve walls. Preferably, the first sleeve wall includes a discontinuity forming a gap exposing an intermediate portion of the mesh sling 403.

[0063] As depicted, the spacer 400 includes a tissue spacing member 422 at its top side 410.

10 The height 426 of the tissue spacing member 422 may be varied to suit a particular clinical application. When the top side 410 of the spacer 400 is placed under a patient's urethra, as explained below with respect to FIGS. 5A and 5B, the height 426 of the tissue spacing member 422 governs the distance between an intermediate portion 428 of the mesh sling 403 and the patient's tissue, for example, the periurethral tissue. The tissue spacing member 422 can be any 15 shape, for example, convex or concave, such that the spacer 400 easily fits under a patient's urethra, as explained below.

[0064] As shown in FIG. 4E, the sling engaging member 416 of the illustrative spacer 400 includes both step teeth 430A and 430B and spiral teeth 432A and 432B, which function as anchoring mechanisms for engaging the intermediate portion 428 of the mesh sling 403 when the mesh sling 403 is tensioned. When no tension is applied to the mesh sling 403 (*i.e.*, when the operator has not yet begun to cut and remove the sleeve 405 from the patient's body), the mesh sling 403 sits loosely in the sling engaging member 418, without engagement by either the step teeth 430A and 430B or the spiral teeth 432A and 432B. In one embodiment, both the step teeth 430A and 430B and the spiral teeth 432A and 432B are tapered toward the front side 414 of the 25 spacer 400. When the medical operator is ready to remove the spacer 400 from the sling assembly 402, the taper of the step teeth 430A and 430B and the spiral teeth 432A and 432B facilitate the process.

[0065] The illustrative spacer 400 also includes a receptacle 434 having an inner wall 436, which forms, for example, an archway 438, which is substantially U-shaped. Alternatively, the 30 receptacle 434 may form any other suitable geometrical shape, including, but not limited to, an angular (*e.g.*, an open ended polygon, such as a rectangle or triangle) or curved (*e.g.* substantially

semicircular) shape. As depicted, the second sleeve wall 409, or alternatively, both the first sleeve wall 407 and the second sleeve wall 409, thread through the sleeve engaging members 420A-420D. The sleeve 403 forms a sleeve bridge 440 at the base of the archway 434, between the sleeve slots 420B and 420C. In other words, the spacer 400 distances the sleeve bridge 440 away from the mesh sling 403, thereby enabling a medical operator to cut the sleeve bridge 440 without inadvertently also cutting the mesh sling 403.

[0066] FIG. 5 depicts a perspective side view of the spacer 400 and sling assembly section 402 of FIGS. 4C-4E employing an insert 442 according to another illustrative embodiment of the invention. The insert 442, for example, a plug, for mating within the receptacle 434 and holding a portion of the sleeve 405 in place within the receptacle 434. The spacer 400 and the sling assembly 402 can be preassembled before its placement in the patient's body. Once the insert 442 is removed, the sleeve bridge 440 may be cut thereby creating sleeve parts 444A and 444B, without risk of the mesh sling 403 also being inadvertently cut. Alternatively, prior to insertion of the sling assembly in the patient, the sleeve 405 can be cut to form the sleeve parts 444A and 444B. The plug 442 is then placed within the receptacle 434 to hold the sleeve parts 444A and 444B in place against the inner wall 436. So assembled, the sling assembly 402 and spacer 400 can then be delivered to the medical operator. Because the medical operator only has to remove the plug 442 from within the receptacle 434 of the spacer 400, and no sleeve cutting is required during sling delivery, the risk of damaging the sling 403, for example, from inadvertent cutting, during placement is reduced.

[0067] FIG. 6A depicts a perspective side view of the spacer 400 and sling assembly section 402 of FIG. 4C, positioned adjacent the urethra 600 of a patient, and FIG. 6B depicts a perspective side view of the illustrative spacer 400 and sling assembly section 402 of FIG. 6A after the sleeve bridge is cut, for example, subsequent to removal of the insert 442. The removal of the insert 442 and cutting of the sleeve 405 causes the sleeve parts 444A and 444B to hang free in the archway 434. Alternatively, the physician may leave the plug 442 in place and cut the sleeve 405 at a point, for example, between the sleeve slots 420A and 420B, thereby creating the sleeve part 444A, and at a point between the sleeve slots 420C and 420D, thereby creating the sleeve part 444B. As in the case of the embodiments of FIGS. 1-3B, by grasping the sleeve ends 602 and 604 and pulling, the medical operator can then remove the sleeve 405 from the patient's body, for example, through a surgical site at the abdominal wall, leaving the mesh sling 403 and

the spacer 400 in place in the patient's body. The spacer 400 can then be removed, for example, via the patient's vagina.

[0068] Referring also to FIGS. 4A and 4B, during the removal of the sleeve 405 from the patient's body, the friction between the sleeve 405 and the mesh sling 403 causes the mid-length portion 428 of the mesh sling 403 to tension against step teeth 430A and 430B and spiral teeth 432A and 432B. As such, the spacer 400 prevents the mid-length portion 428 of the mesh sling 403 from moving beyond the mesh slot 418 during the sleeve 405 removal process. In other words, the mid-length portion 428 of the mesh sling 403 remains, throughout the sleeve removal process, in the mesh slot 418, under the top side 410 of the spacer 400, and, consequently, 10 directly below the patient's urethra 600.

[0069] FIG. 7A depicts a perspective top view of a spacer 700 according to another illustrative embodiment of the invention, and FIG. 7B depicts a perspective top view of the illustrative spacer 700 of FIG. 7A employed with an exemplary sling assembly section 702. Referring to FIGS. 7A and 7B, the illustrative spacer 700 includes a sling engaging member 704 having a cantilever beam 706 as an anchoring mechanism. In the depicted embodiment, the cantilever beam 706 has an inverted T-shape. Alternatively, the cantilever beam 706 may assume other shapes. The cantilever beam 706, in a similar fashion to the step teeth 430A and 430B and the spiral teeth 432A and 432B of the spacer of FIGS. 4A-6B, engages a mid-length portion 708 of a mesh sling 710 when the mesh sling 710 is tensioned. The spacer 700 also includes sleeve 15 engaging members 712A and 712B, which function substantially like the sleeve engaging members 420A and 420D, respectively, of the spacer 400 of FIG. 4.

[0070] Referring particularly to FIG. 7B, the second sleeve wall 712, or, alternatively, both the first sleeve wall 714 and the second sleeve wall 712, loop under a base 716 of the first side 718 of the spacer 700 and under a base 720 of the second side 722 of the spacer 700, rather than 20 through sleeve engaging members, such as the sling engaging members 432B and 432C of the spacer 400 of FIG. 4, to form a sleeve bridge 724. In an alternative embodiment, the second sleeve wall 712, or, alternatively, both the first sleeve wall 714 and the second sleeve wall 712, may be disconnected at a point between the base 716 and the base 720 and held in place against the inner wall 726 of the archway 728 by a plug, such as the plug 442 of FIG. 5. As illustrated, 25 the intermediate portion 708 of the mesh sling 710 is placed in the sling engaging member 704 and loops under the cantilever beam 706.

[0071] In operation, as the sleeve 730 is pulled off the mesh sling 710, intermediate portion 708 of the mesh sling 710 tensions and deflects the cantilever beam 706 into an opposing face (e.g., a face 732), thereby pinning the intermediate portion 708 of the mesh sling 710 between the cantilever beam 706 and the face 732. Following removal of the sleeve 730 from the patient's body, the cantilever beam 706 relaxes, thereby allowing for the removal of the intermediate portion 708 of the mesh sling 710 from the mesh slot 704.

[0072] FIG. 8A depicts a perspective front view of a spacer 800 according to another illustrative embodiment of the invention, and FIG. 8B depicts a perspective side view of the spacer 800 of FIG. 8A employed with an exemplary sling assembly section 802. The spacer 800 includes an elongated shaft member 804 extending between a sling engaging member 806 and a sleeve engaging member 808. The elongated shaft member 804 has a proximal end 824 and a distal end 826 and includes two walls 810 and 812 extending along its length and forming a channel 814 from the proximal end 824 to the distal end 826 for traversal by an intermediate portion 816 of the sleeve wall 818. In one embodiment, the sleeve engaging member 808 may be, for example, U-shaped for forming a sleeve bridge 822, such as the sleeve bridge 440 of FIG. 6A, across its terminal end 820 for facilitating cutting of the second sleeve wall 818 by a medical operator. Alternatively, the sleeve engaging member 808 may be any suitable shape such as, for example, V-shaped or rectangularly-shaped.

[0073] With the spacer 800 and the sling assembly 802 engaged, the intermediate portion 816 of the second sleeve wall 818, or, alternatively, both the first sleeve wall 817 and the second sleeve wall 818, thread through the channel 814 of the elongated shaft member 804 and loop over span 820 of the U-shaped sleeve engaging member 808 to form the sleeve bridge 822, as indicated by arrow 828. The sleeve ends 830 and 832 then thread through the sleeve slots 806A and 806B, respectively, and function similarly to the sleeve slots 712A and 712B of FIGS. 7A and 7B. In a similar fashion to operation of the mesh slot 704 of the spacer 700 of FIGS. 7A and 7B, the intermediate portion 834 of the mesh sling 836 threads through the mesh slot 838.

[0074] One advantage of the spacer 800 is that the elongated shaft member 804 presents the sleeve bridge 822 to the medical operator at a greater distance from the mesh sling 836 than do the previously described embodiments. This increased distance further simplifies the process of cutting the sleeve bridge 822, and further eases the process of removing the sleeve from the patient's body. Moreover, the elongated shaft member 804 makes the task of removing the

spacer 800 from the patient's body easier, as the medical operator need not reach as far into the patient's body to grasp the spacer 800 and remove it.

[0075] FIG. 9 is a perspective view of an spacer 900 having a similar configuration to the illustrative spacer 800 of FIGS. 8A and 8B, but including an elongated shaft member 902 bent at 5 an angle 904, of up to about 90 degrees, relative to the top side 906 of the spacer 900. An advantage of this configuration is that positions the sleeve engaging member 908 to ease the procedure of cutting the sleeve bridge during removal of the sleeve from the patient's body.

[0076] FIG. 10A depicts a perspective side view of a spacer 1000 according to another 10 illustrative embodiment of the invention, and FIG. 10B depicts a plan view of the spacer 1000 of FIG. 10A employed with an exemplary sling assembly section 1002. As shown, the spacer 1000 includes a shaft 1004, an extension 1006, and a pin 1008 extending from the spacer 1000. The shaft 1004 includes a proximal end 1010, a distal end 1012, and first 1014 and second 1016 walls forming a channel 1018 extending from the proximal end 1010 to the distal end 1012. The first wall 1014 includes a first face 1020 and the second wall 1016 has a second face 1122. The 15 spacer 1000 also includes first 1024 and second 1026 sleeve engaging members. As depicted, a first sleeve slot 1028 passes from the through the first 1014 and second 1016 walls across the channel 1018. The first sleeve engaging member 1024 extends at an angle 1032 from a base face 1020 of the wall 1014. Similarly, the second sleeve engaging member 1026 extends at an angle 1034 from the face 1022 of the second wall 1016. Preferably, the angles 1032 and 1034 are 20 substantially equal. In some configurations, the angles 1042 and 1034 are both about 180 degrees. In another embodiment, the sleeve engaging members 1024 and 1026 are curved, rather than angled, with respect to the first 1014 and second 1016 walls. In another alternative embodiment, the sleeve engaging members 1024 and 1026 form a substantially V-shape. The extension 1006 extends distally from the distal end 1012 of the shaft 1004. The pin 1008 is fixed 25 to and extends substantially orthogonally from the extension 1006.

[0077] Referring particularly to FIG. 10B, the second sleeve surface 1042, or, alternatively, both the first sleeve surface 1040 and the second sleeve surface 1042 thread across a top side 1040 of the first wall 1014, through the channel 1018, through the first sleeve slot 1028, across a base 1054 of the first sleeve engaging member 1024, across a base 1056 of the second sleeve 30 engaging member 1026, through the second sleeve slot 1030, back through the channel 1018, and across a top side 1058 of the second wall 1016. In this way, the second sleeve wall 1042, or,

alternatively, both first sleeve wall 1040 and the second sleeve wall 1042, form a sleeve bridge 1060 between the first sleeve engaging member 1024 and the second sleeve engaging member 1024. Preferably, the pin 1008 passes through the weave of an intermediate portion 1048 of the mesh sling 1046, so as to act as an anchoring mechanism that engages the intermediate portion 5 1048 of the mesh sling 1046. As such, the pin 1008 prevents movement of the intermediate portion 1046 of the mesh sling 1048 when the mesh sling 1048 is tensioned during removal of the sleeve 1044 from the patient's body.

10 [0078] FIG. 11A depicts a perspective top view of a spacer 1100 according to another illustrative embodiment of the invention. The spacer 1100 is generally tubular in shape and includes a wall 1101 defining a lumen 1102 extending between first 1104 and second 1106 apertures. As depicted in FIG. 11A, the spacer 1100 includes a slot shaped aperture 1108 formed at an intermediate location in the tube wall 1101 between the first 1104 and second 1106 apertures. The aperture 1108 effectively divides the spacer 1100 along the center line 1110 into two substantially equal halves 1100a and 1100b.

15 [0079] FIG. 11B depicts a perspective side view of the illustrative spacer 1100 of FIG. 11A, bent at its mid-line 1110 according to illustrative embodiment of the invention. So bent, the two spacer halves 1100a and 1100b are formed into a substantially V-shape, with a vertex at 1112 and one leg including a first lumen section 1102a and the other leg including the second lumen section 1102b. In an alternative illustrative embodiment, the first and second spacer halves 20 1100a and 1100b may form a substantially U-shaped or rectangularly-shaped spacer. In other illustrative embodiments, the tubular shape of the spacer 1100 may be flattened, with the aperture 1108 formed on one of the resulting sides. As in the case of the previously discussed spacer embodiments, the spacer 1100 may be made of a polymer or other suitable material.

25 [0080] FIG. 11C depicts a perspective side view of the spacer 1100, bent in accord with the illustrative embodiment of FIG. 10B, employed with an exemplary sling assembly section 1114. The sling assembly 1114 includes a mesh sling 1116, at least partially enclosed by a sleeve 1118. As depicted, the second sleeve surface 1122, or, alternatively, both the first sleeve surface 1120 and the second sleeve surface 1122, pass through the aperture 1108 at the vertex 1112. The second sleeve surface 1122 passes through the first lumen section 1102a, through the first 30 aperture 1104, across and into the second aperture 1106, through the second lumen section

1102b and back out the aperture 1108 to form a sleeve bridge 1130 between the first aperture 1104 and the second aperture 1106.

[0081] FIG. 11D depicts a perspective side view of the spacer 1100 and sling assembly 1114 configuration of FIG. 11C employing and anchoring mechanism according to an illustrative embodiment of the invention. In the embodiment of FIG. 11D, the anchoring mechanism includes a suture 1134 threaded through the weave of an intermediate portion 1124 of the mesh sling 1116, so as to engage the intermediate portion 1124. The suture 1134, in a similar fashion to the sleeve wall 1122, passes through the aperture 1108 and the first 1102a and second 1102b lumen sections, and forms a suture bridge 1134. As such, the suture 1132 prevents movement of the intermediate portion 1124 of the mesh sling 1116 when the mesh sling 1116 is tensioned during removal of the sleeve 1118 from the patient's body.

[0082] FIG. 11E depicts a bottom view of the spacer 1100 further formed to include a truss 1136 according to an illustrative embodiment of the invention. FIG. 11F depicts a perspective top view of the spacer 1100 of FIG. 10E. FIG. 11G depicts a perspective side view of the spacer 1100 of FIG. 10E bent along its mid-line 1110, according to further illustrative embodiment of the invention. Referring to FIGS. 11E-11G, first 1138 and second 1140 substantially parallel slits are formed in the wall 1101 to form the truss 1136 to be substantially symmetrical about the center line 1110. The spacer 1100 may or may not be flattened during this process. As depicted in FIGS. 11F and 11G, the spacer 1100 is then folded into the V-shape of FIG. 11B, causing the truss 1136 to fold out of and away from the wall 1101, thereby creating a slot 1142, between slits 1138 and 1140.

[0083] FIG. 11H depicts the spacer 1100 configured as depicted in FIG. G and employed with the exemplary sling assembly 1114. In the illustrative embodiment of FIG 11H, the sleeve 1118 traverses the spacer 1100 to form the sleeve bridge 1130 in the same manner as described above with respect to the embodiment of FIG. 11C. Additionally, the intermediate portion 1124 of the sling 1116 passes through the slot-shaped aperture 1108 out the aperture 1142 in the first spacer half 1100a and rests on top of the truss 1136. An anchoring mechanism, for example, an anchor tube 1150, may be used to secure the intermediate mesh portion 1124 against the truss 1136. As indicated by arrow 1152, the anchor tube 1150 is placed between the intermediate sling portion 1124 and the wall 1101. In the illustrative embodiment, an lower portion 1154 of the outer of the anchor tube 1150 pins the intermediate sling portion 1124 against the truss 1136,

while an upper portion 1156 of the outer surface of the anchor tube 1150 rests against the outer wall 1101 of the spacer 1100 near the vertex 1112. As such, the anchor tube 1150 prevents movement of the intermediate sling portion 1124 when the mesh sling 1116 is tensioned during removal of the sleeve 1118 from the patient's body.

5 [0084] The truss 1136, in this embodiment of the invention, also prevents the spacer halves 1101a and 1101b from moving towards one another when the sleeve 1116 is tensioned to place the spacer 1100 under the patient's urethra. Moreover, as illustrated, this embodiment of the invention allows for a greater amount of slack in the intermediate sling portion 1124.

10 [0085] FIG. 12 depicts the sling assembly 1200 including two sleeves 1202 and 1204 employed with a tubular spacer 1206 according to another illustrative embodiment of the invention. In this embodiment, the sleeve tails 1208 and 1210 extend from the proximal ends 1212 and 1214 of the sleeves 1202 and 1204, respectively, and fit into the tubular spacer 1206. In the illustrative embodiment, the tubular spacer 1206 is substantially cylindrical. Alternatively, the tubular spacer 1206 can be flattened. The tubular spacer 1206 can be formed from any suitable material, 15 such as a rigid or tearable polymer material.

[0086] FIG. 13 depicts a further illustrative embodiment of the tubular spacer 1206, wherein the sleeve tails 1208 and 1210 are fixed to an inner surface 1216 of the tubular spacer 1206, for example, by gluing or heating.

20 [0087] FIG. 14 depicts another illustrative embodiment of the tubular spacer 1206, in which the spacer 1206 is formed from the same or a similar plastic materials as the sleeves 1202 and 1204, such as, for example, polyethylene. The sleeve tails 1210A and 1210B extend from the proximal end 1218 of the tubular spacer 1206. Once the sling assembly 1220 and the spacer 1206 are correctly positioned, the medical operator removes the sleeves 1020 and 1204 from about the sling 1216. In this embodiment, the sleeve tails 1210A and 1210B couple to the tubular spacer 25 1206 by, for example, heat sealing. The physician grasps the sleeve tails 1210A and 1210B and peels the sleeve tails 1210A and 1210B apart, as indicated by arrows 268.

30 [0088] As depicted in FIG. 15, in peeling apart the sleeve tails 1210A and 1210B, the soft plastic tubular spacer 1206 is separated into a portion 1206A and 1206B. By grasping the distal ends 1220A and 1220B of the sleeves ends 1210A and 1210B, the physician removes both portions of the now separated soft plastic tubular spacer 1206A and 1206B, and the sleeves 1202 and 1204 from the patient's body, leaving behind the sling 1216 in the patient's body.

[0089] Additionally, it should be noted that Applicants intend any operable embodiments existing between the systems, methods, devices, and applications thereof herein incorporated by reference and the illustrative embodiments described above to be considered within the scope of the inventions disclosed herein and, as such, claimable subject matter. The spacers as previously 5 described may be made in various configurations and from various materials suited to the application in which they are used, so long as the spacer functions to create a space between the sling and the portion of the sleeve to be separated for removal, thereby decreasing the chance of damaging the sling during sleeve removal. Also, spacers of the invention can be colored so as to enhance visibility in the body and its location along the sleeve so as to provide a visual indicator 10 of approximately the midpoint of the sling so as to facilitate proper placement of the sling in the body.

[0090] Variations, modifications, and other implementations of what is described herein will occur to those of ordinary skill without departing from the spirit and scope of the invention. Accordingly, the invention is not to be limited only to the preceding illustrative description.

15 [0091] What is claimed is: